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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,423	04/12/2004	Stephen P.A. Fodor	3594.1	2561

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EXAMINER

LIU, SUE XU

ART UNIT PAPER NUMBER

1639

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/822,423	<b>Applicant(s)</b> FODOR, STEPHEN P.A.	
	<b>Examiner</b> Sue Liu	<b>Art Unit</b> 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 9-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 9-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## DETAILED ACTION

### Claim Status

Claims 8, and 12-22 have been canceled as filed on 6/16/06;

Claims 1-7 and 9-11 are being examined in this application.

### *Priority*

1. This application claims benefit of provisional application 60/462,508 filed on 04/11/2003.

### *Claim Rejections Withdrawn*

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-7 and 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 of the instant application recite a method for analyzing a nucleic acid sample by using different nucleic acid affinity matrices and labels. The steps of the methods are not clearly defined. For example, the step of "labeling of the first and second sets of nucleic acids with different labels" could be carried out before the hybridization step. How is each set of nucleic acid labeled differentially with different labels when they are in the same sample? In addition, it is also not clear whether the "collections of beads" recited in Claim 3 are the same bead array directed in Claim 11. Therefore, the instant claims failed to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. The above rejection under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, as set forth in the previous office action is withdrawn in part. Applicants state in the Reply entered 6/16/06, at p. 4, para 4, that "the claim language of claim 11 is clear and indicates that the 'collection of beads' of claim 3 is not the same as the 'collection of bead array' of claim

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11.” In light of applicants’ statement that the “collection of beads” and the “collection of bead array are different from each other, the rejection is withdrawn in part. However, applicants’ argument does not overcome the rejection over the indefiniteness of the claimed method steps recited in Claim 1, as discussed below.

**Claim Rejections Maintained**

5. Claims 1-7 and 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The previous rejection is maintained for the reasons of record as set forth on p. 3 of the Office action mailed on 12/16/05.

**Discussion and Answer to Argument**

6. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

*Applicants argue that “Claim 1 is NOT indefinite as the scope of the claim includes different methods for labeling two populations of nucleic acids. Many methods are well known in the art.” (pg 4 of the Reply.)*

The rejection set forth in the previous Office action was not only directed at the “labeling” step itself. The rejection was in regard to the claim as a whole. The relationship of the step of selecting the labeling of the nucleic acids, and the step of

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detecting are unclear. The claim as written is incomplete for omitting essential steps, and such omission amounting to a gap between the steps. The claim fails to clearly state the steps of the methods and the relationships among the different steps. For example, the step of "labeling of the first and second sets of nucleic acids with different labels" could be carried out before the hybridization step. It is not clear how the first and second sets of nucleic acids are differentially labeled before the hybridization step. The claimed method (as recited in Claim 1) requires detecting and/or distinguishing the "first" and the "second" set of nucleic acids by labeling the different sets of nucleic acids. However, the claimed method also requires a selection step of the two different sets of nucleic acids before the labeling step. It is not clear how the different steps are connected, and the order of the steps that is required to carry out the claimed method.

**Claim Rejections Maintained**

***Claim Rejections - 35 USC § 102***

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
8. Claims 1-7 and 9-11 as amended or originally filed are rejected under **35 U.S.C. 102(b)** as being anticipated by Fodor et al (US 5,800,992; 09/01/1998). The previous rejection is maintained for the reasons of record as set forth in the Office action, mailed 12/16/05, at p. 4-5.

Discussion and Answer to Argument ('992)

9. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

*Applicants state that "In the arguments presented by the Examiner for rejection the present claims, the Examiner states that the references read on the claimed invention which the applicant accepts. However, for a reference to anticipate the claims, the claims should read on the prior art rather than the reverse"(emphasis provided by applicants). (Reply at p. 5, para 3).*

Applicant's above argument does not overcome the instant rejection for anticipation, because the '992 patent teaches the claimed invention. The rejection of record (over US 5,800,992) discussed in detail how the reference ('992 patent) describes all elements of the claimed invention.

*Applicants further argue that "The Examiner has not pointed out that each and every element of the claims is disclosed by the cited references. For example, the Examiner fails to point to paragraph 256 of USFN 5,800,992 as disclosing two sets of affinity matrices, but the applicant's representative could not find such disclosure in the cited section. Therefore, withdrawal of these rejections is respectfully requested." (Reply at p. 5, para 5).*

Contrary to applicant's assertion, the previous Office action has discussed every elements of the claimed invention (see p. 4-5 of the previous Office action). The rejection

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of the previous Office action is herein incorporated by reference in its entirety. Except for one example (as discussed below), applicants have not specifically point out which instantly claimed element is not taught by the reference. That is applicants have not specifically demonstrate how the cited reference fails to teach every element of the claimed method.

As an example of the alleged failure of the Office action to demonstrate the teaching of the reference anticipates the claimed invention, applicants argue *“For example, the Examiner fails to point to paragraph 256 of USFN 5,800,992 as disclosing two sets of affinity matrices, but the applicant's representative could not find such disclosure in the cited section”*. However, the anticipatory rejection (102) over the ‘992 patent did not cite “paragraph 256” anywhere in the discussion (p. 4-5 of the previous Office action). The cited “paragraph 256” is found in the text of the 103 obviousness rejection on page 9 of the previous Office action, and the argument is addressed in the 103 section of the instant Office action.

10. Claims 1, 2, 4-7, 9 and 10 as amended or originally filed are rejected under **35 U.S.C. 102(b)** as being anticipated by Fodor et al (US 6,309,822 B1; 10/30/2001). The previous rejection is maintained for the reasons of record advanced on p. 5-6 of the Office action mailed on 12/16/05.

Discussion and Answer to Argument ('822)

11. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

*Applicants state that "In the arguments presented by the Examiner for rejection the present claims, the Examiner states that the references read on the claimed invention which the applicant accepts. However, for a reference to anticipate the claims, the claims should read on the prior art rather than the reverse"(emphasis provided by applicants). (Reply at p. 5, para 3).*

Applicant's above argument does not overcome the instant rejection for anticipation, because the '822 patent teaches the claimed invention. The rejection of record (over US 6,309,822) discussed in detail how the reference ('822 patent) describes all elements of the claimed invention.

*Applicants also argue "The Examiner has not pointed out that each and every element of the claims is disclosed by the cited references." (Reply at p. 5, para 3).*

Applicants did not specifically point out the supposed error for the rejection over the '822 patent. Contrary to applicant's assertion, the previous Office action has discussed every elements of the claimed invention (see Pages 5-6 of the previous Office action). The rejection over the '822 patent as set forth in the previous Office action is herein incorporated by reference in its entirety.



12. Claims 1-7 and 9-11 as amended or originally filed are rejected under 35 U.S.C. 102(e) as being anticipated by Fodor et al (US 6,576,424 B2; 06/10/2003; filed 1/25/2001). The previous rejection is maintained for the reasons of record as set forth in the Office action, mailed 12/16/05, at p. 6-7.

Discussion and Answer to Argument ('424)

13. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

*Applicants state that "In the arguments presented by the Examiner for rejection the present claims, the Examiner states that the references **read on** the claimed invention which the applicant accepts. However, for a reference to anticipate the claims, the claims should read on the prior art rather than the reverse"(emphasis provided by applicants). (Reply at p. 5, para 3).*

Applicant's above argument does not overcome the instant rejection for anticipation, because the '424 patent teaches the claimed invention. The rejection of record (over US 6,576,424) discussed in detail how the reference ('424 patent) describes all elements of the claimed invention.

*Applicants also argue "The Examiner has not pointed out that each and every element of the claims is disclosed by the cited references." (Reply at p. 5, para 3).*

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Applicants did not specifically point out the supposed error for the rejection over the '424 patent. Contrary to applicant's assertion, the previous Office action has discussed every elements of the claimed invention (see Pages 6-7 of the previous Office action), and their equivalence in the reference patent ('424 patent). The rejection over the '424 patent as set forth in the previous Office action is herein incorporated by reference in its entirety.

14. Claims 1, 2, 4-7, 9 and 10 as amended or originally filed are rejected under 35 U.S.C. 102(e) as being anticipated by Fodor et al (US 6,551,784 B2; 4/22/2003; filed 5/9/2001). The previous rejection is maintained for the reasons of record as set forth in the Office action, mailed 12/16/05, at p. 7-8.

Discussion and Answer to Argument ('784)

15. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

*Applicants state that "In the arguments presented by the Examiner for rejection the present claims, the Examiner states that the references read on claimed invention which the applicant accepts. However, for a reference to anticipate the claims, the claims*

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*should read on the prior art rather than the reverse” (emphasis provided by applicants).*

*(Reply at p. 5, para 3).*

Applicant's above argument does not overcome the instant rejection for anticipation, because the '784 patent teaches the claimed invention. The rejection of record (over US 6,551,784) discussed in detail how the reference ('784 patent) describes all elements of the claimed invention.

*Applicants also argue “The Examiner has not pointed out that each and every element of the claims is disclosed by the cited references.” (Reply at p. 5, para 3).*

Applicants did not specifically point out the supposed error for the rejection over the '784 patent. Contrary to applicant's assertion, the previous Office action has discussed every elements of the claimed invention (see Pages 7-8 of the previous Office action), and their equivalence in the reference patent ('784 patent). The rejection over the '424 patent as set forth in the previous Office action is herein incorporated by reference in its entirety.

**Claim Rejections Maintained**

***Claim Rejections - 35 USC § 103***

16. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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17. Claims 1-7 and 9-11 as amended or originally filed are rejected under **35 U.S.C. 103(a)** as being unpatentable over Lichtenwalter (US 5,683,875; 11/04/1997), in view of Fodor et al (US 5,800,992; 09/01/1998). The previous rejection is maintained for the reasons of record as set forth in of the Office action, mailed 12/16/05, at p. 8-10.

*Discussion and Answer to Argument (103)*

18. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

*Applicants argue that "the Examiner has not pointed out where in the references it is discussed the selecting of a fist [sic] and a second set of nucleic acids from the nucleic acid sample with a first and second nucleic acid affinity matrices with two different sets of nucleic acids. The Examiner indicates that Lichtenwalter does not teach two different sets of nucleic acid samples or two different sets of nucleic acid affinity matrices and indicates that paragraph 256 of Fodor et al teaches it. However, the applicant's representative does not see where in the references it is discussed the nucleic acid affinity matrices." (Reply at p. 5-6, bridging para).*

Contrary to applicants' assertion, the combination of the references (Lichtenwalter and Fodor) renders the instant claimed invention obvious. The specific teachings of each of the reference was cited in the previous Office action, and also restated below. The particular citation "paragraph 256" was cited for the purpose of

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demonstrating the advantages of Fodor's teaching as whole, which included the detection of different sets of interaction.

As applicants have pointed out, and as stated in the previous Office action, the Lichtenwalter reference does not teach two different sets of nucleic acid samples or two different sets of nucleic acid affinity matrices.

However, Fodor et al teaches a method of detecting nucleic acid sequences in two or more collections of nucleic acid molecules (Claim 1 of the reference), which would read on two different sets (first and second sets) of nucleic acids. The Fodor reference also teaches "contacting" and "hybridization" of the "first collection of labeled nucleic acid" and "at least a second collection of labeled nucleic acid" to an array of polynucleotides (which would read on oligonucleotide probes) bound to a solid surface (See Claim 1 of the reference). This would read on hybridizing the first and second sets of nucleic acids to two different nucleic acid affinity matrices because the array of polynucleotides would contain complementary nucleic acids to the different sets of nucleic acids.

As discussed above, Fodor et al teach detecting two sets of nucleic acid samples with two sets of nucleic acid affinity matrices. The Fodor reference further teaches that the invention, i.e. detecting two sets of nucleic acids with two sets of nucleic acid affinity matrices, is advantageous because the taught method also for high resolution testing of many different interactions simultaneously ('992 patent, Col. 30, lines 20+, which is para [256]). See Paragraph [256] of the Detailed Description of the '992 patent; the Paragraph is quoted below:

“In a similar manner, the antigenic determinants found on a protein may very well define the cell class. For example, immunological T-cells are distinguishable from B-cells because, in part, the cell surface antigens on the cell types are distinguishable. Different T-cell subclasses can be also distinguished from one another by whether they contain particular T-cell antigens. The present invention provides the possibility for high resolution testing of many different interactions simultaneously, and the definition of new cell types will be possible.”  
(‘992 patent at Col. 30, lines 20+)

Therefore, it would have been *prima facie* obvious for a person of ordinary skill at the time the invention was made to generate a method for detecting different nucleic acid samples with different nucleic acid probes attached to solid substrate (such as beads) by using distinguishable fluorescent labels.

A person of ordinary skill in the art would have been motivated at the time of the invention was made to modify the method taught by Lichtenwalter by generating two different probe sets and using two different nucleic acid samples, because such a method offers the advantage of high resolution testing of many different interactions simultaneously, as taught by Fodor et al discussed above.

A person of ordinary skill in the art would have reasonable expectation of success of achieving detecting two sets of nucleic acid samples simultaneously with two different probe sets, because all the necessary techniques for detecting nucleic acid using immobilized probes are known in the art as taught by Lichtenwalter and Fodor et al. The known and routine techniques include generating immobilized nucleic acid probes, preparing nucleic acid samples, nucleic acid hybridization, nucleic acid labeling with fluorescent labels, detecting fluorescent labels, and using microarray for detecting nucleic acid hybridization, which are all taught by Lichtenwalter and Fodor et al.

**Claim Rejections Maintained*****Double Patenting***

19. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**The following obviousness-type double patenting rejections are maintained:**

20. Claims 1-7 and 9-11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 5,800,992. The previous rejection is maintained for the reasons of record as set forth in the Office action, mailed 12/16/05, at p. 10-11.

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21. Claims 1, 2, and 4-7 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,309,822 B1. The previous rejection is maintained for the reasons of record as set forth in the Office action, mailed 12/16/05, at p. 12.

22. Claims 1-7 and 9-11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16, 17 and 39-64 of U.S. Patent No. 6,576,424 B2. The previous rejection is maintained for the reasons of record as set forth in the Office action, mailed 12/16/05, at p. 12-13.

23. Claims 1, 2, and 4-7 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 and 20 of U.S. Patent No. 6,551,784 B2. The previous rejection is maintained for the reasons of record as set forth in the Office action, mailed 12/16/05, at p. 13-14.

*Discussion and Answer to Argument (ODP)*

24. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

*Applicants traversed all the above ODP rejections together in the Reply, at p. 6. Applicants argue that "A terminal disclaimer will be filed upon allowance of the present application."*



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It is noted that the above outstanding ODP rejections are not provisional rejections. Applicants may file terminal disclaimers in compliance with 37 CFR 1.321(c) or 1.321(d) to overcome an actual ODP rejection based on a nonstatutory double patenting ground.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue Liu whose telephone number is 571-272-5539. The examiner can normally be reached on M-F 9am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached at 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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8/7/2005

PETER PARAS, JR.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

A handwritten signature in cursive script, appearing to read "Peter Paras, Jr.", is positioned below the printed name and title.